



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Ashley J. BIRKETT	)
	) Attorney Docket:
U.S. Serial No.: 10/080,299	) 4564/84273
	) ICC-127.0
Filed: February 21, 2002	)
	) Art Group:
Title: <b>INFLUENZA IMMUNOGEN AND</b>	) 1645
<b>VACCINE</b>	)
	) Confirmation No:
Examiner: Not yet assigned	) 1149

INFORMATION DISCLOSURE STATEMENT

U.S. Patent and Trademark Office  
2011 South Clark Place  
Customer Window  
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Arlington, Virginia 22202

Sir:

Pursuant to 37 C.F.R. §1.97, a list of documents that may be material to the examination of this application is provided on the attached Form PTO/SB/08. Listed Documents A1 to A118 are U.S. patents, foreign patents and pertinent articles that may be relevant to the examination of the present application. Copies of Documents A1 to A118 are bound and enclosed herewith.

No inferences should be drawn that the attached list represents a comprehensive investigation, or that any material

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disclosed is equivalent to the subject invention. In addition, none of the documents that have publication dates prior to the priority date of the above application anticipate the invention in this application.

The cited documents disclose numerous specific features. There has been no attempt to list each and every feature disclosed by each document. The Examiner is requested to review the documents and determine the extent of the materiality of the document disclosures with respect to the present invention.

The discussion of any art and the citation of any document herein is not to be construed as an admission that the art or document disclosure is necessarily within the invention field of endeavor, that the art or document disclosure is necessarily prior in time to a particular date which may be relevant to the instant patent application, and/or that the art or document disclosure is otherwise necessarily prior art as defined by the patent law with respect to the instant invention and application.

Also, there is reserved the right to later set forth how the instant invention is distinguished over the disclosure of any document or other art, including the disclosures of the

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INFORMATION DISCLOSURE STATEMENT

art and documents recited herein, that may be cited by the Examiner in rejecting a claim in the instant patent application.

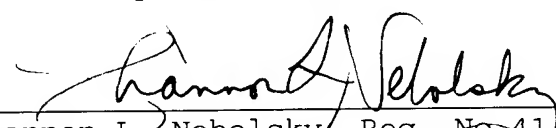
The recitation herein of the art and documents is not to be construed as an assertion that more pertinent art could not possibly be in existence.

No fee or petition is believed to be necessary. However, should any fee be needed, please charge our Deposit Account No. 23-0920, and deem this paper to be the required petition.

The Examiner is requested to phone the undersigned should any questions arise that can be dealt with over the phone to expedite this prosecution.

Respectfully submitted,

By

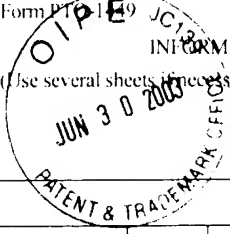
  
Shannon L. Nebolsky, Reg. No. 41,217  
Attorney for Applicants

Enclosures:

Form PTO/SB/08  
Six Bound Volumes of Art (A1-A118)  
Postcard

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(Rev. 5-92) Comparable to Form PTO-1449 INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket No. ICC-127.0 (4564-84273)		Serial No. 10,080,299		
		Applicants Ashley J. Birkett						
		Filing Date February 21, 2002		Group				
U.S. PATENT DOCUMENTS								
*Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate	
	A1	4,539,205	09/03/1985	Goodman, et al.	514	45		
	A2	4,643,992	02/17/1987	Goodman, et al.	514	45		
	A3	4,767,842	08/30/1988	Stevens	530	324		
	A4	4,818,527	04/04/1989	Thornton, et al.	424	88		
	A5	4,882,145	11/21/1989	Thornton, et al.	424	88		
	A6	4,987,237	01/22/1991	Myers, et al.	549	222		
	A7	5,011,828	04/30/1991	Goodman, et al.	514	45		
	A8	5,023,179	06/11/1991	Lam, et al.	435	172.3		
	A9	5,057,540	10/15/1991	Kensil, et al.	514	25		
	A10	5,093,318	03/03/1992	Goodman, et al.	514	45		
	A11	5,110,732	05/05/1992	Benfey et al.	435	172.3		
	A12	5,143,726	09/01/1992	Thornton, et al.	424	88		
	A13	5,297,441	03/29/1994	Smith et al.	73	860		
	A14	5,387,744	02/07/1995	Curtiss, III et al.	424	235.1		
	A15	5,618,988	04/08/1997	Hauptmann, et al.	800	205		
	A16	5,656,472	08/12/1997	Ausich et al.	435	193		
	A17	5,679,880	10/21/1997	Curtiss, III et al.	800	205		
	A18	5,709,879	01/20/1998	Barchfeld, et al.	424	450		
	A19	5,888,799	03/30/1999	Curtiss, III	435	252.3		
	A20	5,990,085	11/23/1999	Ireland, et al.	514	12		
	A21	6,024,961	02/15/2000	Curtiss, III et al.	424	200		
	A22	6,086,901	07/11/2000	O'Hagan, et al.	424	283.1		
	A23	6,231,864	05/15/2001	Birkett	424	189.1		
FOREIGN PATENT DOCUMENTS								
		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
	A24	GB 2,122,204 A	01/11/1984	GB				
	A25	WO 91/13922	09/19/1991	PCT				
	A26	EP 399 843 B1	11/28/1990	EP				
	A27	WO 95/17210	06/29/1995	PCT				
	A28	EP 421635 B1	04/10/1991	EP				
					Date Considered			
*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.								

(Rev. 5/92) Comparable to Form PTO-159		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket No. ICC-127.0 (4564-84273)		Serial No. 10/080,299	
 INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)				Applicants  Ashley J. Birkett			
				Filing Date February 21, 2002		Group	
FOREIGN PATENT DOCUMENTS							
	A29	WO 96/02555	02/01/1996	PCT			
	A30	WO 96/33739	10/13/1996	PCT			
	A31	EP 671,948 B1	09/20/1995	EP			
	A32	EP 689,454 B1	01/03/1996	EP			
	A33	WO 99/07839	02/18/1999	PCT			
	A34	WO 99/40934	08/19/1999	PCT			
	A35	WO 99/52549	10/21/1999	PCT			
	A36	WO 00/32625	06/08/2000	PCT			
	A37	WO 01/27281	4/19/2001	PCT			
	A38	WO 01/41759	06/14/2001	PCT			
	A39	WO 01/98333	12/27/2001	PCT			
	A40	WO 02/13765	02/21/2002	PCT			
	A41	WO 02/14478	02/21/2002	PCT			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	A42	BENFEY et al., "Regulated Genes in Transgenic Plants", <i>Science</i> (April 1989) <b>244</b> :174-181					
	A43	BIRKETT et al., "Development of a Vaccine to Prevent Falciparum Malaria Infection" - Poster presented by J. Haron at the Center for Advanced Technology and Medicine (CABM) Symposium, Rutgers University Medical Center on October 13-14, 1999					
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	A45	BIRNBAUM et al., "Hepatitis B Virus Nucleocapsid Assembly: Primary Structure Requirements in the Core Protein", <i>J. Virol.</i> (1990) <b>64</b> :3319-3330					
	A46	BLACK, et al., "Antibody Response to the M2 Protein of Influenza A Virus Expressed in Insect Cells", <i>J. of General Virol.</i> (1993) <b>74</b> :143-146					
	A47	BOTTCHEER et al., "Determination of the fold of the core protein of hepatitis B virus by electron cryomicroscopy", <i>Nature</i> (1997) <b>386</b> :88-91					
	A48	CLARKE et al., "Expression and Immunological Analysis of Hepatitis-B Core Fusion Particles Carrying Internal Heterologous Sequences", <i>Vaccines</i> (1991) <b>91</b> , Cold Spring Harbor Laboratory, New York, pp.313-318					
	A49	COLUCCI et al., "Identification of a Major Hepatitis B Core Antigen (HBcAg) Determinant by Using Synthetic Peptides and Monoclonal Antibodies", <i>J. of Immunology</i> (December 1988) <b>141</b> :4376-4380					
	A50	CONWAY et al., "Visualization of a 4-helix bundle in the hepatitis B virus capsid by cryo-electron microscopy", <i>Nature</i> (1997) <b>386</b> :91-94					
				Date Considered			
*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

(Rev. 5/92) Comparable to Form PTO-1449  INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket No. ICC-127.0 (4564-84273)	Serial No. 10:080,299
		Applicants Ashley J. Birkett			
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OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)					
	A51	CREGG et al., " <i>Pichia pastoris</i> as a Host System for Transformation", <i>Molecular and Cellular Biology</i> (December 1985) <b>5(12)</b> : 3376-3385			
	A52	CREGG et al., "High-Level Expression and Efficient Assembly of Hepatitis B Surface Antigen in the Methylophilic Yeast, <i>Pichia Pastoris</i> ", <i>Bio/Technology</i> (May 1987) <b>5</b> :479-485			
	A53	DEIKMAN et al., "Interaction of a DNA Binding Factor with the 5'-Flanking Region of an Ethylene-Responsive Fruit Ripening Gene from Tomato", <i>EMBO J.</i> (1988) <b>7(11)</b> :3315-3320			
	A54	DEIKMAN et al., "Organization of Ripening and Ethylene Regulatory Regions in a Fruit-Specific Promoter from Tomato", <i>Plant Physiol.</i> (1992) <b>100</b> :2013-2017			
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	A56	DIRITA et al., "Deletion Analysis of the Mannopine Synthase Gene Promoter in Sunflower Crown Gall Tumors and <i>Agrobacterium tumefaciens</i> ", <i>Mol. Gen. Genet.</i> (1987) <b>207</b> :233-241			
	A57	ENGELHARD et al., "The Insect Tracheal System: A Conduit for the Systemic Spread of <i>Autographa Californica</i> M Nuclear Polyhedrosis Virus", <i>Proc. Natl. Acad. Sci., USA</i> (April 1994) <b>91</b> :3224-3227			
	A58	GALIBERT et al., "Nucleotide sequence of the hepatitis B virus genome (subtype ayw) cloned in <i>E. coli</i> ", <i>Nature</i> (October 1979) <b>281</b> :646-650			
	A59	GALIBERT et al., "Nucleotide Sequence of a Cloned Woodchuck Hepatitis Virus Genome: Comparison with the Hepatitis B Virus Sequence", <i>J. Virol.</i> (January 1982) <b>41(1)</b> :51-65			
	A60	GALLINA et al., "A Recombinant Hepatitis B Core Antigen Polypeptide with the Protamine-Like Domain Deleted Self-Assembles into Capsid Particles but Fails to Bind Nucleic Acids", <i>J. Virol.</i> (1989) <b>63(11)</b> :4645-4652			
	A61	GRAHAM et al., "A New Technique for the Assay of Infectivity of Human Adenovirus 5 DNA", <i>Virol.</i> (1973) <b>52</b> :456-467			
	A62	INADA et al., "Synthesis of hepatitis B virus e antigen in <i>E. coli</i> ", <i>Virus Res.</i> (1989) <b>14</b> :27-48			
	A63	ISAGULIANTS et al., "Immunogenic Combinations of HIV-1 B- and Heterologous T-cell Epitopes", <i>Immunol. Ltr.</i> (1994) <b>42</b> :173-178			
	A64	"IUPAC-IUB Commission on Biochemical Nomenclature A One-Letter Notation for Amino Acid Sequences <sup>1-3</sup> Tentative Rules", <i>J. Biol. Chem.</i> (July 1968) <b>243(13)</b> :3557-3559			
	A65	KELLER et al., "Specific Expression of a Novel Cell Wall Hydroxyproline-Rich Glycoprotein Gene in Lateral root Initiation", <i>Genes &amp; Development</i> (1989) <b>3</b> :1639-1646			
	A66	KRATZ et al., "Native display of complete foreign protein domains on the surface of hepatitis B virus capsids", <i>Proc. Natl. Acad. Sci., USA</i> (1999) <b>96</b> :1915-1920			
	A67	KRUGER et al., "Chimeric Virus-Like Particles as Vaccines", <i>Biol. Chem.</i> (March 1999) <b>380</b> :275-276			
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)					
	A68	LAMB et al., "In Vitro Influenza Virus-Specific Antibody Production in Man: Antigen-Specific and HLA-Restricted Induction of Helper Activity Mediated by Cloned Human T Lymphocytes", <i>J. of Immunology</i> (October 1982) <b>129(4)</b> :1465-1470			
	A69	LAZDINA et al., "Priming of Cytotoxic T Cell Responses to Exogenous Hepatitis B Virus Core Antigen is B Cell Dependent", <i>J. of General Virol.</i> (2003) <b>84</b> :139-146			
	A70	LINDSTROM et al., "Expression of Soybean Lectin Gene Deletions in Tobacco", <i>Developmental Genetics</i> (1990) <b>11</b> :160-167			
	A71	LONDONO et al., "Immunisation of Mice Using <i>Salmonella typhimurium</i> Expressing Human Papillomavirus Type 16 E7 Epitopes Inserted into Hepatitis B Virus Core Antigen", <i>Vaccine</i> (1996) <b>14(6)</b> :545-552			
	A72	LUCKOW, "Insect Cell Expression Technology" Chapter 7 in <u>Protein Engineering: Principle and Practice</u> , J.L. Cleland et al. eds., Wiley-Liss, Inc. (1996) pages 183-218			
	A73	LUCKOW et al., "Efficient Generation of Infectious Recombinant Baculoviruses by Site-Specific Transposon-Mediated Insertion of Foreign Genes into a Baculovirus Genome Propagated in <i>Escherichia coli</i> ", <i>J. Virol.</i> (August 1993) <b>67(8)</b> :4566-4579			
	A74	MAASSEN et al., "Comparison of three different recombinant hepatitis B virus core particles expressed in <i>Escherichia coli</i> ", <i>Arch. Virol.</i> (1994) <b>135</b> :131-142			
	A75	MATTEUCCI et al., "Synthesis of Deoxyoligonucleotides on a Polymer Support", <i>J. Am. Chem. Soc.</i> (1981) <b>103</b> :3185-3191			
	A76	METZGER et al., "Proline-138 is essential for the assembly of hepatitis B virus core protein", <i>J. Gen. Virol.</i> (1998) <b>79</b> :587-590			
	A77	MILICH et al., "The Nucleocapsid of Hepatitis B Virus is Both a T-Cell-Independent and a T-Cell-Dependent Antigen", <i>Science</i> (1986) <b>234(4782)</b> :1398-1401			
	A78	MILICH et al., "Conversion of Poorly Immunogenic Malaria Repeat Sequences into a Highly Immunogenic Vaccine Candidate", <i>Vaccine</i> (2002) <b>20</b> :771-788			
	A79	NARDELLI-HAEFLIGER et al., "Oral and Rectal Immunization of Adult Female Volunteers with a Recombinant Attenuated <i>Salmonella typhi</i> Vaccine Strain", <i>Infect. and Immun.</i> (December 1996) <b>64(12)</b> :5219-5224			
	A80	NASSAL et al., "An Intramolecular Disulfide Bridge between Cys-7 and Cys61 Determines the Structure of the Secretory Core Gene Product (e Antigen) of Hepatitis B Virus", <i>J. Virol.</i> (July 1993) <b>67(7)</b> :4307-4315			
	A81	NEIRYNCK et al., "A universal influenza A vaccine based on the extracellular domain of the M2 protein", <i>Nature Med.</i> (October 1999) <b>5(10)</b> :1157-1163			
	A82	ODELL et al., "Identification of DNA Sequences Required for Activity of the Cauliflower Mosaic Virus 35S Promoter", <i>Nature</i> (February 1985) <b>313</b> :810-812			
	A83	ONO et al., "The complete nucleotide sequences of the cloned hepatitis B virus DNA; subtype adr and adw", <i>Nucleic Acids Res.</i> (1983) <b>11(6)</b> :1747-1757			
		Date Considered			
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)					
	A84	PALENZUELA et al., "Purification of the Recombinant Hepatitis B core Antigen, and Its Potential Use for the Diagnosis of Hepatitis B Virus Infection", <i>Biotechnologia Aplicada</i> (2002) <b>19(3)</b> :136-142			
	A85	PASEK et al., "Hepatitis B virus genes and their expression in <i>E. coli</i> ", <i>Nature</i> (December 1979) <b>282</b> :575-579			
	A86	PASZKOWSKI et al., "Direct Gene Transfer to Plants", <i>EMBO J.</i> (1984) <b>3(12)</b> :2717-2722			
	A87	PUMPENS et al., "Hepatitis B Virus Core Particles as Epitope Carriers", <i>Intervirology</i> (1995) <b>38</b> :63-74			
	A88	ROGERS et al., "Improved Vectors for Plant Transformation: Expression Cassette Vectors and New Selectable Markers", <i>Meth. in Enzymol.</i> (1987) <b>153</b> :253-277			
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	A90	SALLBERG et al., "A Malaria Vaccine Candidate Based on a Hepatitis B Virus Core Platform", <i>Intervirology</i> (2002) <b>45</b> :350-361			
	A91	SCHERLE et al., "Functional Analysis of Influenza-Specific Helper T Cell Clones in Vivo", <i>J. Exp. Med.</i> (October 1986) <b>164</b> :1114-1128			
	A92	SCHODEL et al., "Recombinant HBV Core Particles Carrying Immunodominant B-Cell Epitopes of the HBV Pre-S2 Region", <i>Vaccines</i> (1990) <b>90</b> , Cold Spring Harbor Laboratory, New York, pp.193-198			
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	A94	SCHODEL et al., "The Position of Heterologous Epitopes Inserted in Hepatitis B Virus Core Particles Determines Their Immunogenicity", <i>J. Virol.</i> (January 1992) <b>66(1)</b> :106-114			
	A95	SCHODEL et al., "Structure of Hepatitis B Virus Core and e-Antigen", <i>J. Biological Chemistry</i> (1993) <b>268(2)</b> : 1332-1337			
	A96	SCHODEL et al., "Immunity to Malaria Elicited by Hybrid Hepatitis B Virus Core Particles Carrying Circumsporozoite Protein Epitopes", <i>J. Exp. Med.</i> (1994) <b>180(3)</b> :1037-1046			
	A97	SCHODEL et al., "Hybrid Hepatitis B Virus Core-Pre-S Proteins Synthesized in Avirulent <i>Salmonella typhimurium</i> and <i>Salmonella typhi</i> and Oral Vaccination", <i>Infect. Immunol.</i> (1994) <b>62(5)</b> :1669-1676			
	A98	SCHODEL et al., "Hybrid Hepatitis B Virus Core Antigen as a Vaccine Carrier Moiety: I. Presentation of Foreign Epitopes", <i>J. Biotechnol.</i> (1996) <b>44</b> :91-96			
	A99	SCHODEL et al., "Immunization with Hybrid Hepatitis B Virus Core Particles Carrying Circumsporozoite Antigen Epitopes Protects Mice Against <i>Plasmodium yoelii</i> Challenge", <i>Behring Inst. Mitt.</i> (1997) <b>98</b> :114-119			
	A100	SEEGER et al., "Nucleotide Sequence of an Infectious Molecularly Cloned Genome of Ground Squirrel Hepatitis Virus", <i>J. Virol.</i> (August 1984) <b>51(2)</b> :367-375			
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)					
	A101	SEIFER et al., "Assembly and Antigenicity of Hepatitis B Virus Core Particles", <i>Intervirology</i> (1995) <b>38</b> :47-62			
	A102	STAHL, et al., "Hepatitis B Virus Core Antigen: Synthesis in Eschericia coli and Application in Diagnosis", <i>Proc. Natl. Acad. Sci. USA</i> (March 1982) <b>79</b> :1606-1610			
	A103	STOUTE et al., "A Preliminary Evaluation of a Recombinant Circumsporozoite Protein Vaccine Against <i>Plasmodium Falciparum</i> Malaria", <i>N. Engl. J. Med.</i> (1997) <b>336</b> (2):86-91			
	A104	TACKET et al., "Safety and Immunogenicity in Humans of an Attenuated <i>Salmonella typhi</i> Vaccine Vector Strain Expressing Plasmid-Encoded Hepatitis B Antigens Stabilized by the Asd-Balanced Lethal Vector System", <i>Infect. &amp; Immun.</i> (August 1997) <b>65</b> (8):3381-3385			
	A105	TREANOR et al., "Passively Transferred Monoclonal Antibody to the M2 Protein Inhibits Influenza A Virus Replication in Mice", <i>J. Virol.</i> (March 1990) <b>64</b> (3):1375-1377			
	A106	TSUDA et al., "Application of the Human Hepatitis B Virus Core Antigen from Transgenic Tobacco Plants for Serological Diagnosis", <i>Vox Sang</i> (1998) <b>74</b> :148-155			
	A107	TWELL et al., "The 5'-Flanking DNA of a Patatin Gene Directs Tuber Specific Expression of a Chimaeric Gene in Potato", <i>Plant Mol. Biol.</i> (March 1987) <b>9</b> :365-375			
	A108	ULRICH et al., "Core Particles of Hepatitis B Virus as Carrier for Foreign Epitopes", <i>Adv. Virus Res</i> (1998) <b>50</b> :141-182			
	A109	VODKIN et al., "cA Lectin Gene Insertion has the Structural Features of a Transposable Element", <i>Cell</i> (1983) <b>34</b> :1023-1031			
	A110	WASENAUER et al., "Relevance of Cysteine Residues for Biosynthesis and Antigenicity of Human Hepatitis B Virus e Protein", <i>J. Virol.</i> (March 1993) <b>67</b> (3):1315-1321			
	A111	WENZLER et al., "Analysis of a Chimeric Class-I Patatin-GUS Gene in Transgenic Potato Plants: High-Level Expression in Tubers and Sucrose-Inducible Expression in Cultured Leaf and Stem Explants", <i>Plant Mol. Biol.</i> (1989) <b>12</b> :41-50			
	A112	WYNNE et al., "The Crystal Structure of the Human Hepatitis B Virus Capsid", <i>Mol. Cell</i> (June 1999) <b>3</b> :771-780			
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## Applicants

Ashley J. Birkett

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